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(54) **APPARATUS AND METHODS FOR REMOVING LYMPH NODES OR ANCHORING INTO TISSUE DURING A TRANSLUMENAL PROCEDURE**

(75) Inventors: **Annette Fritscher-Ravens**, Bruchhausen-Vilsen (DE); **Vihar C. Surti**, Winston-Salem, NC (US)

(73) Assignee: **Cook Medical Technologies, LLC**, Bloomington, IN (US)

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(58) **Field of Classification Search**

USPC 606/106, 110, 113, 114, 127, 200

See application file for complete search history.

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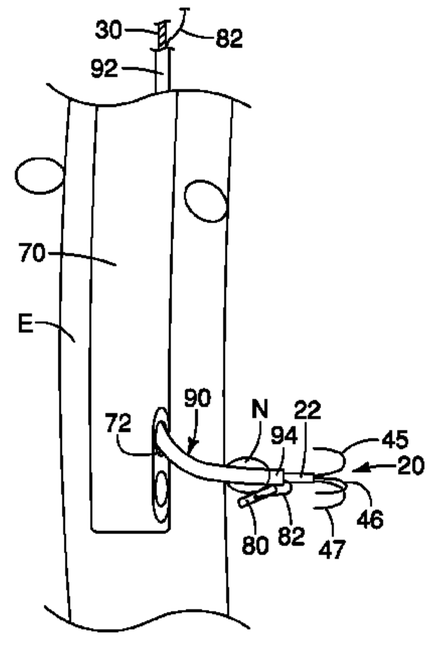
Primary Examiner — Ashley Fishback

(74) *Attorney, Agent, or Firm* — Brinks Gilson & Lione

(57) **ABSTRACT**

The present embodiments provide apparatus and methods suitable for removing lymph nodes or providing a tissue anchor during a translumenal procedure. In one embodiment, an apparatus suitable for facilitating removal of a lymph node comprises an expandable device including at least one deployable member having contracted and expanded states. The deployable member may be delivered in the contacted state to a location distal to the lymph node using an insertion tool adapted to be disposed beyond the lymph node. In the expanded state, the deployable member comprises a configuration sized to at least partially circumferentially surround and engage the lymph node. In an alternative embodiment, the deployable member may anchor into an outer portion of a visceral wall to promote stabilization of a system during a medical procedure.

6 Claims, 10 Drawing Sheets



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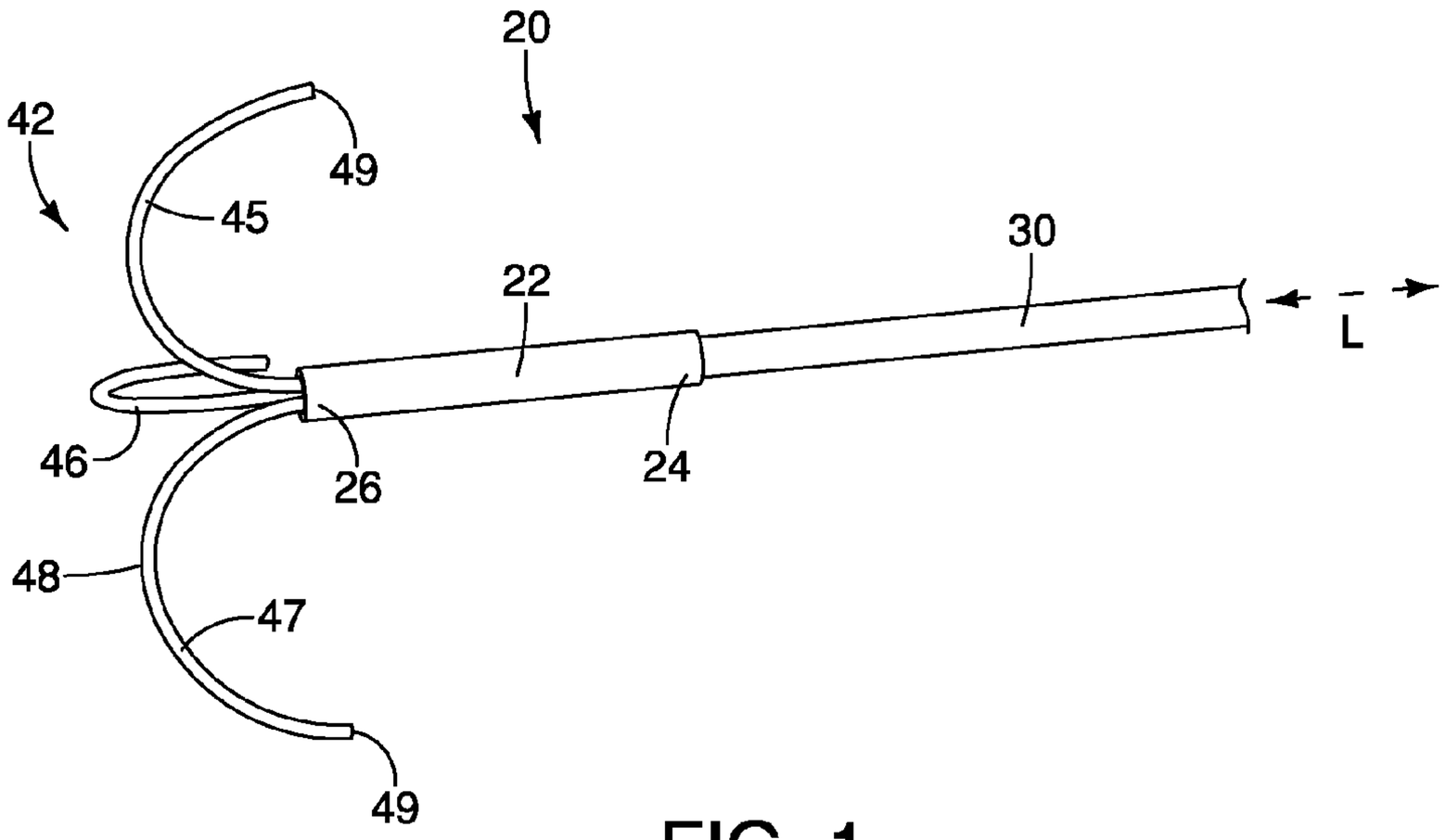


FIG. 1

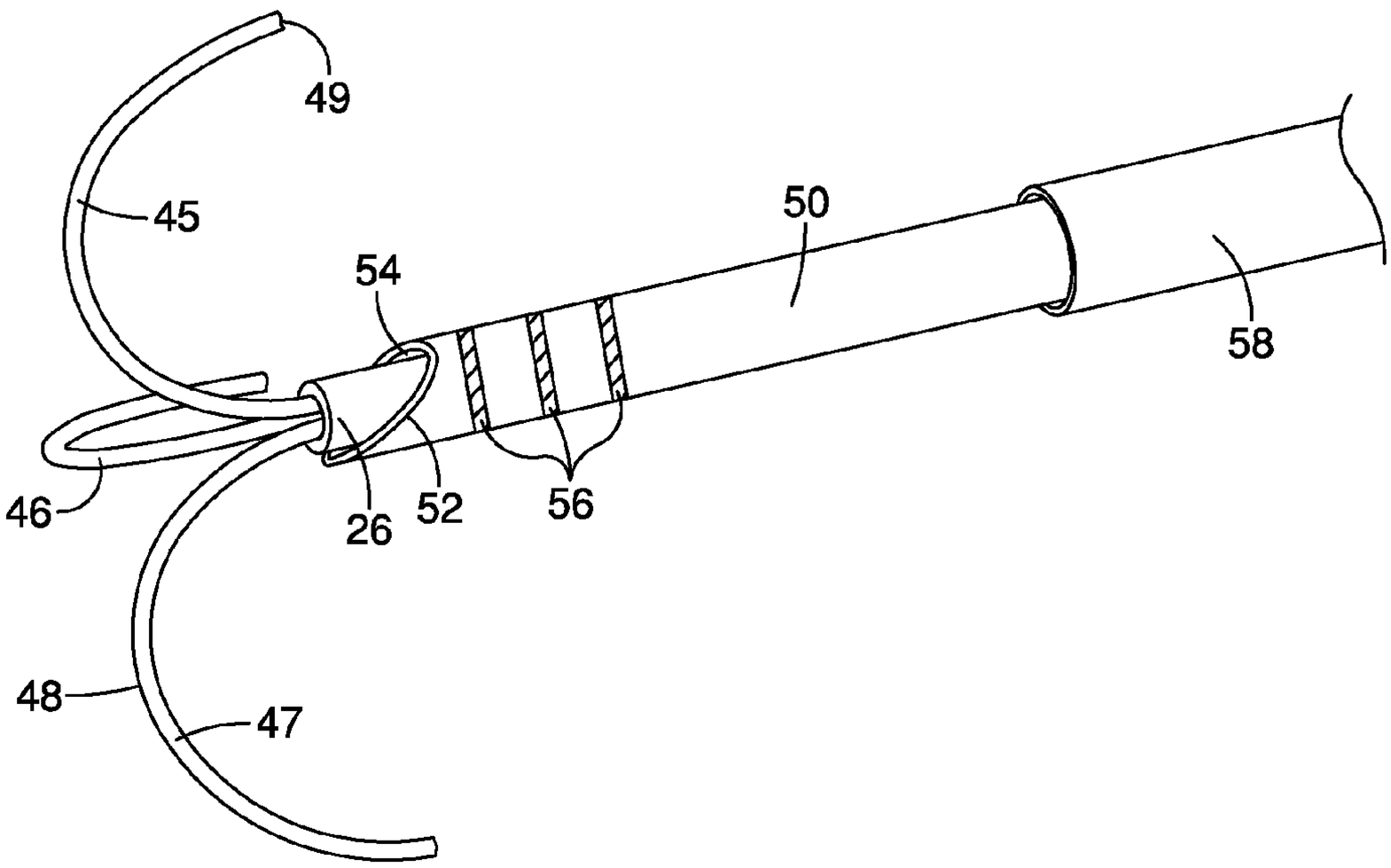


FIG. 2A

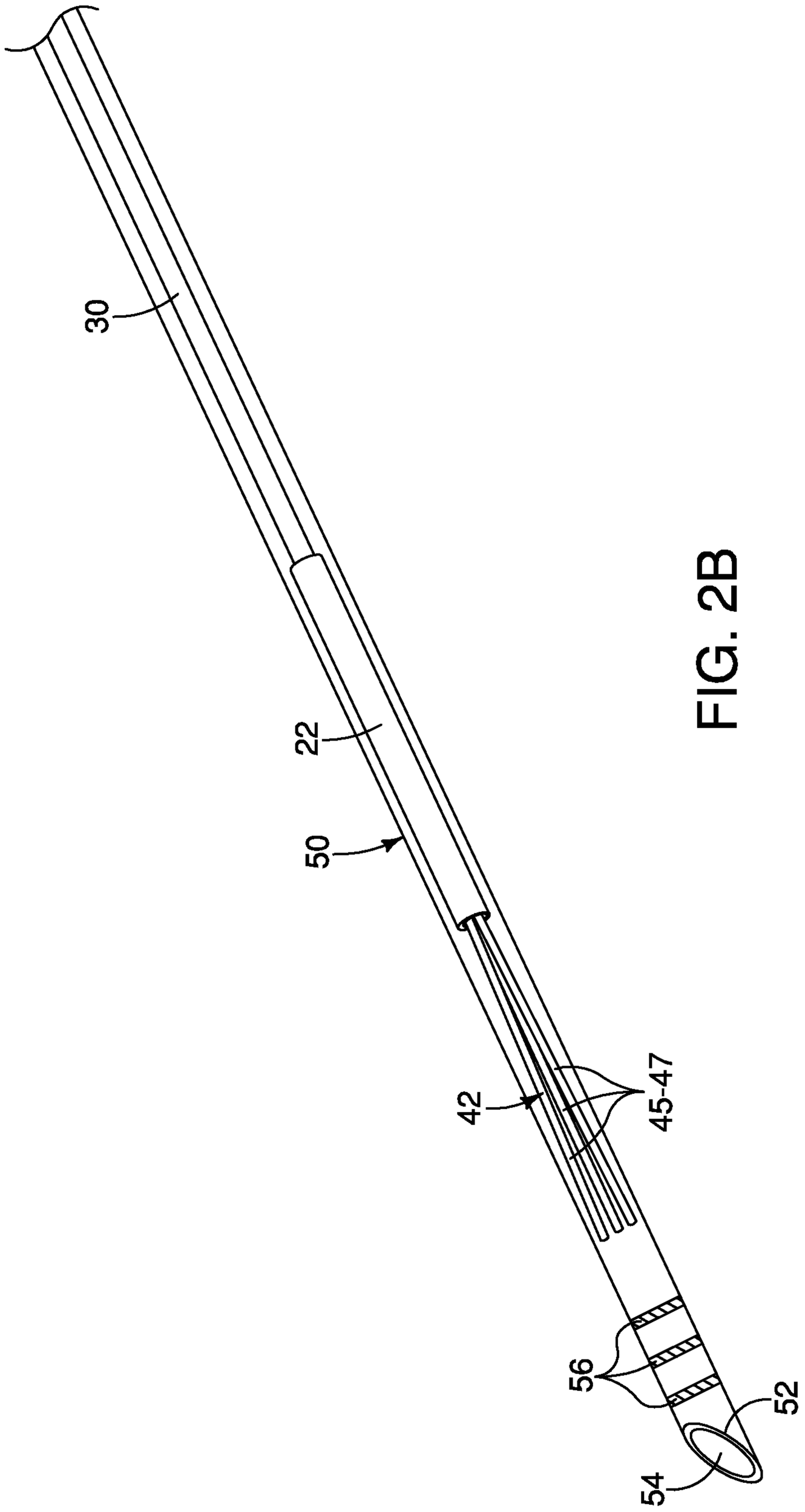


FIG. 2B

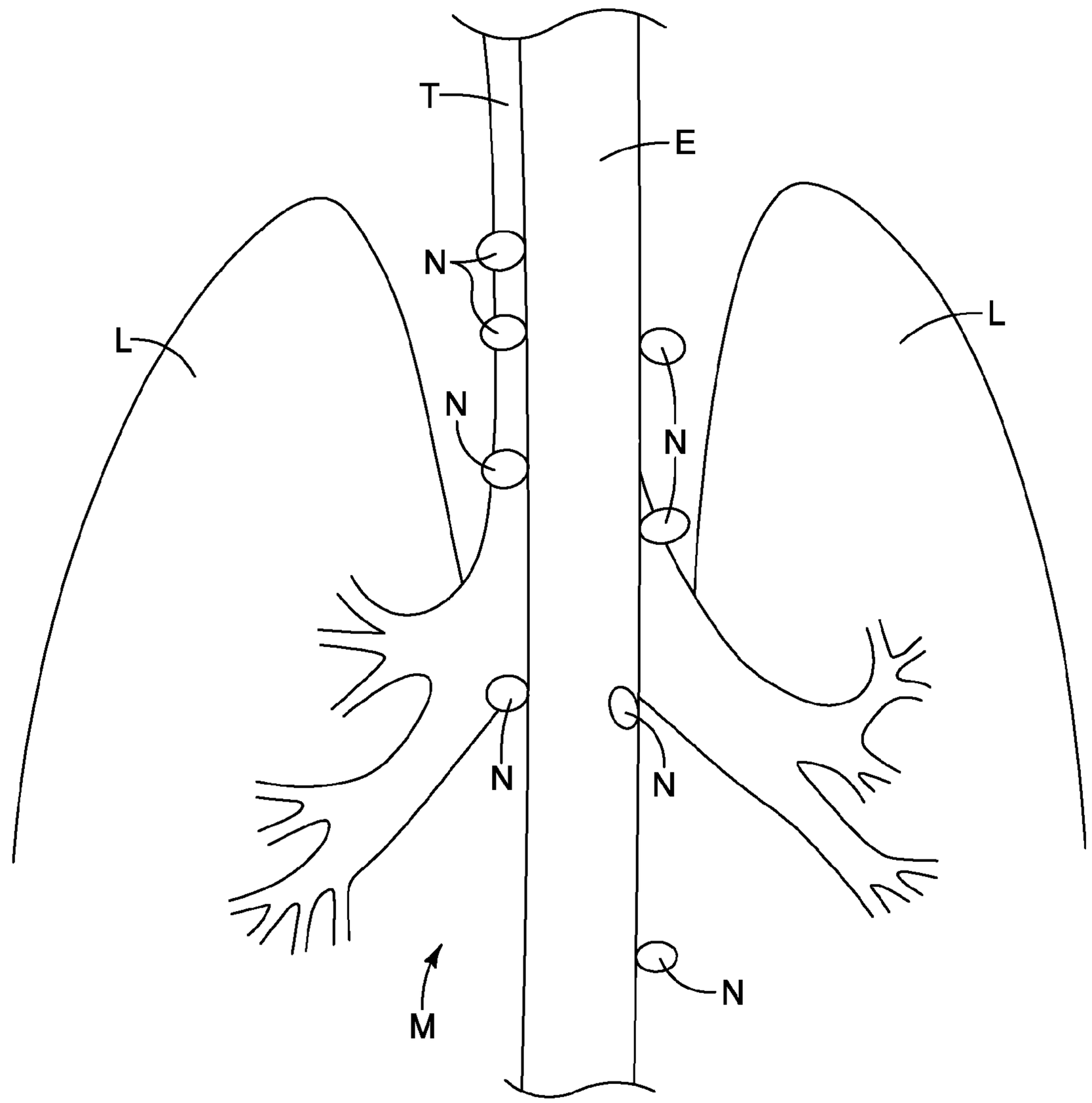


FIG. 3

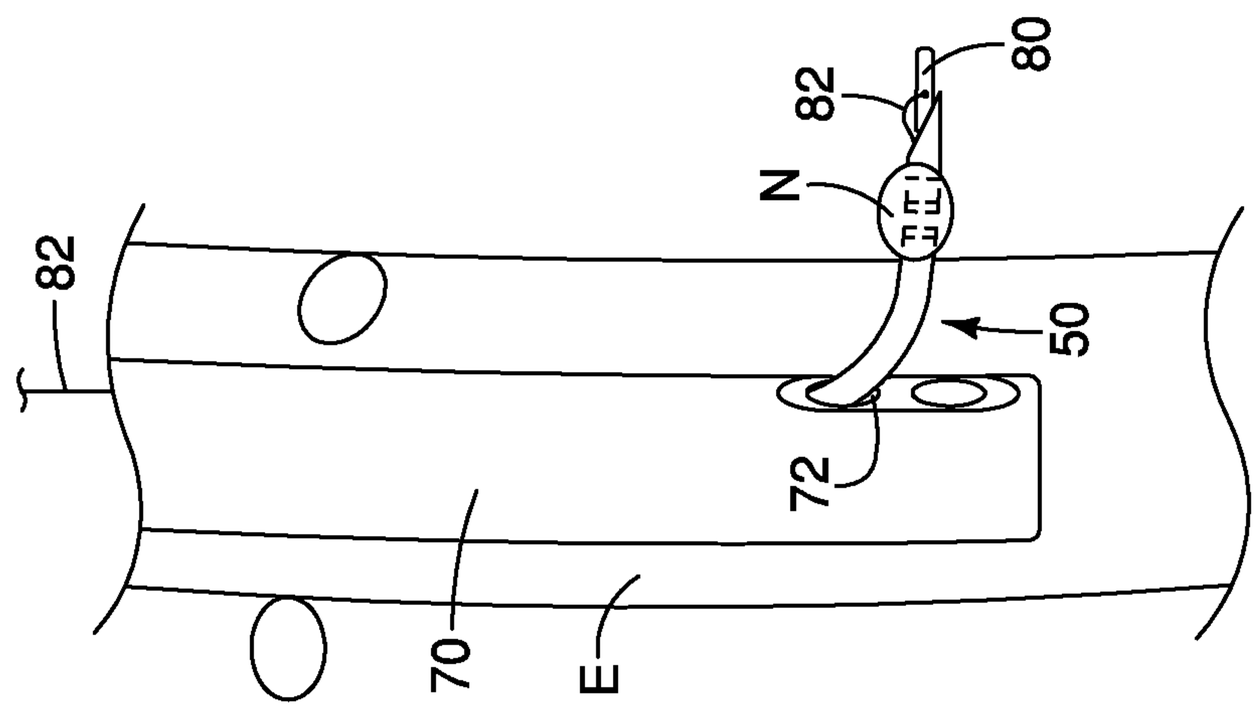


FIG. 6

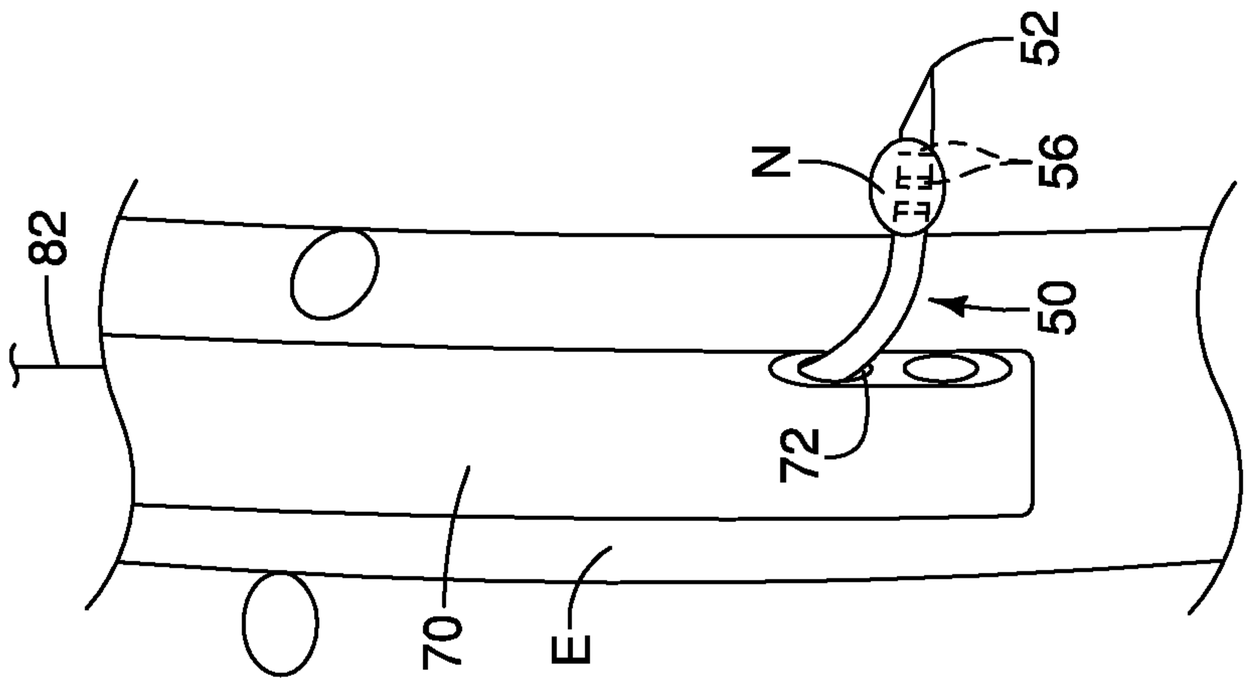


FIG. 5

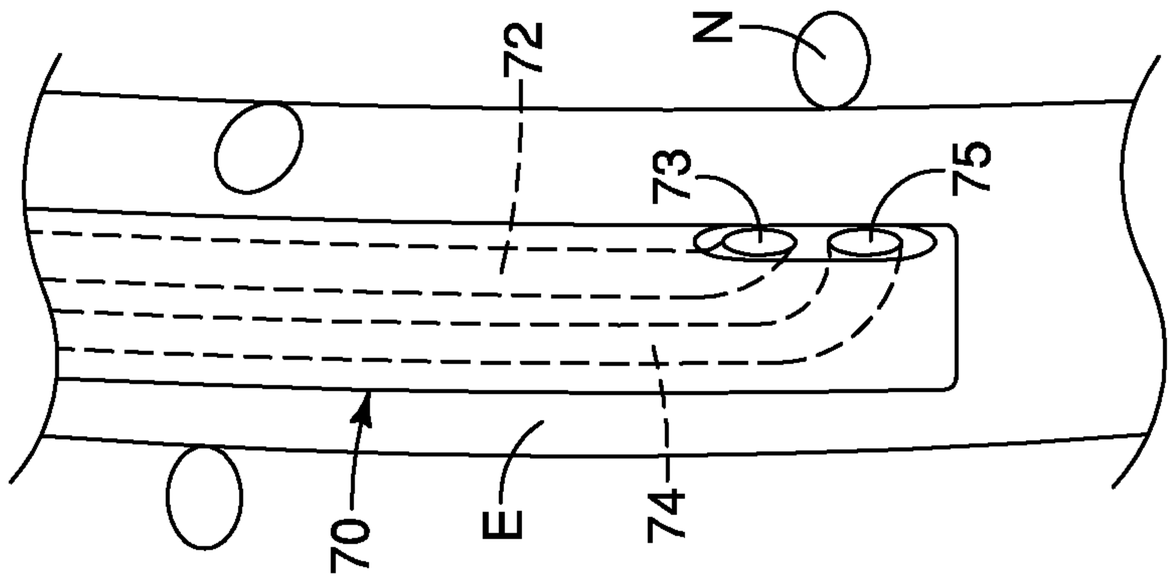


FIG. 4

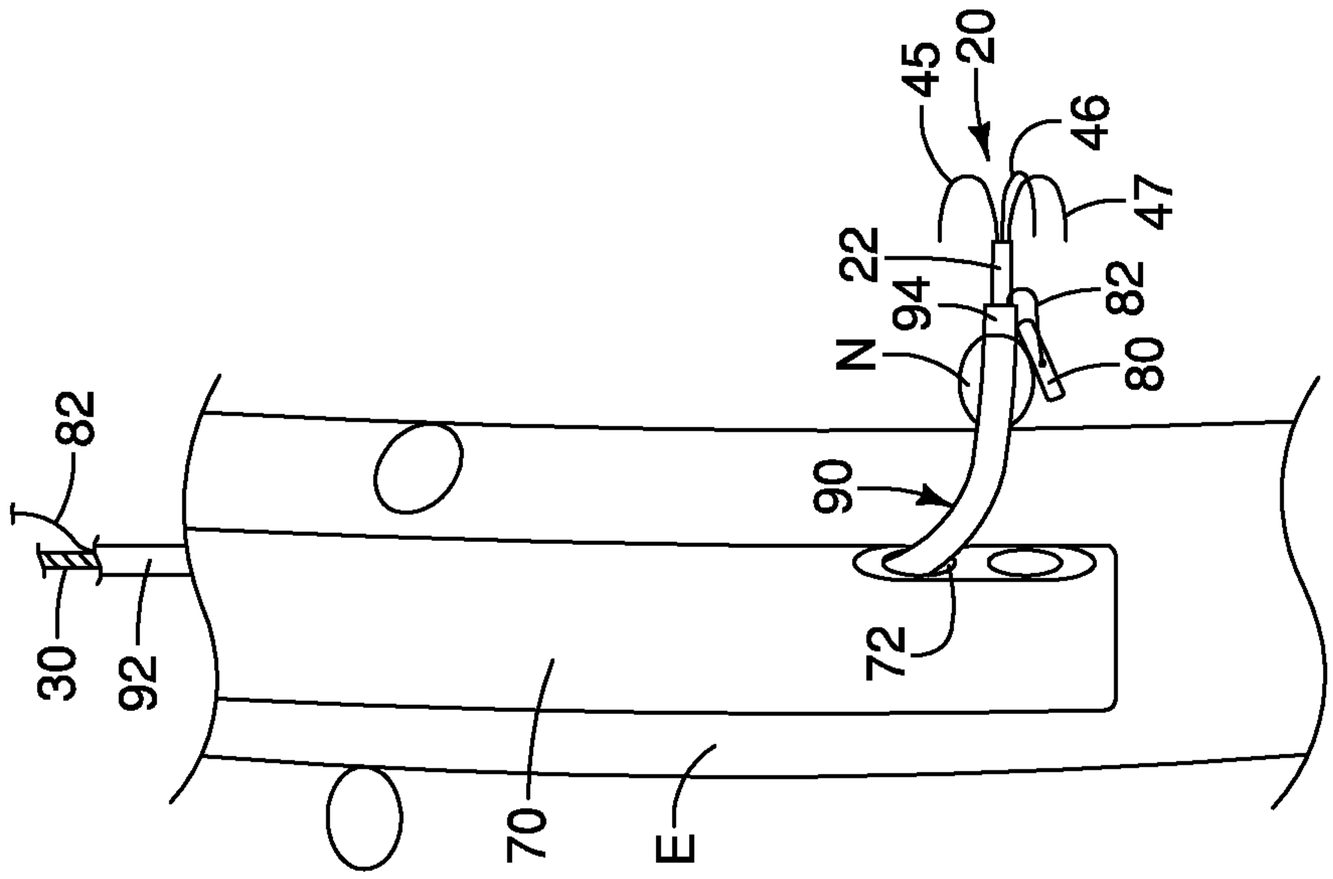


FIG. 9

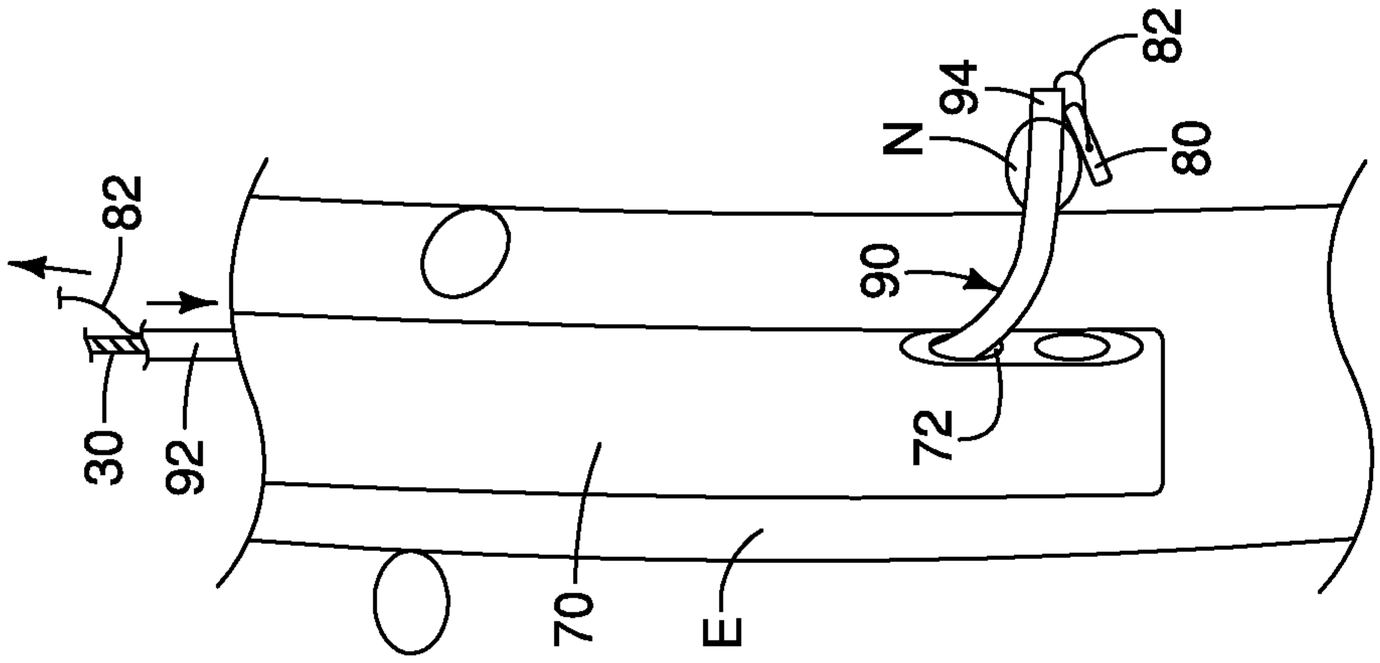


FIG. 8

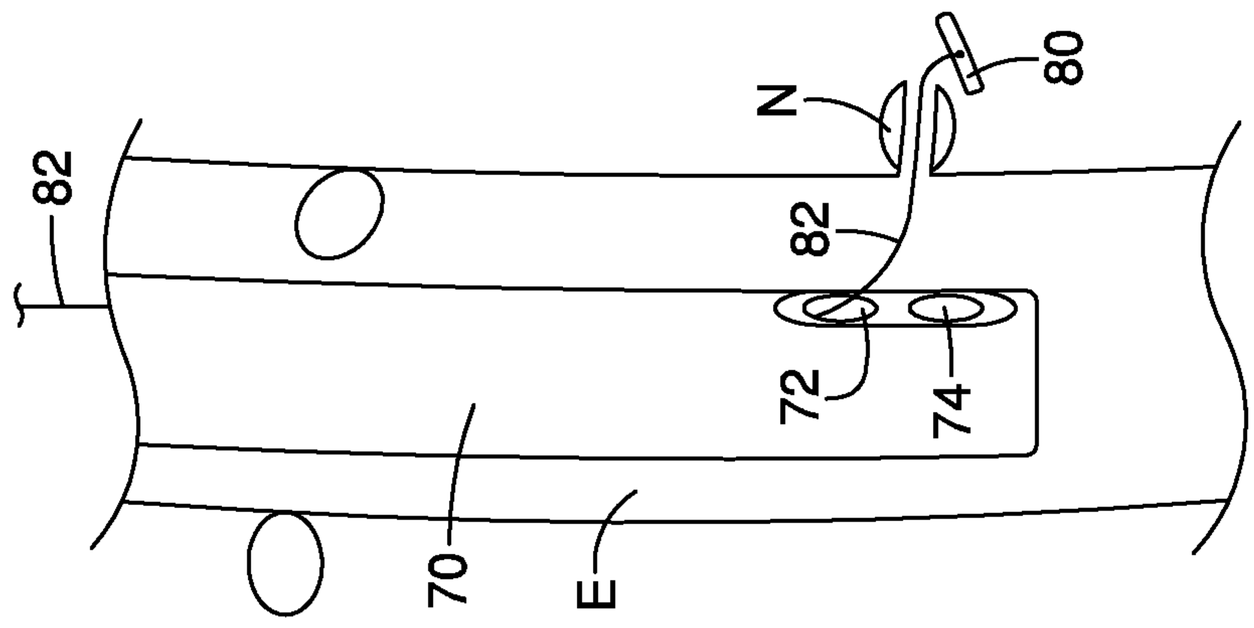


FIG. 7

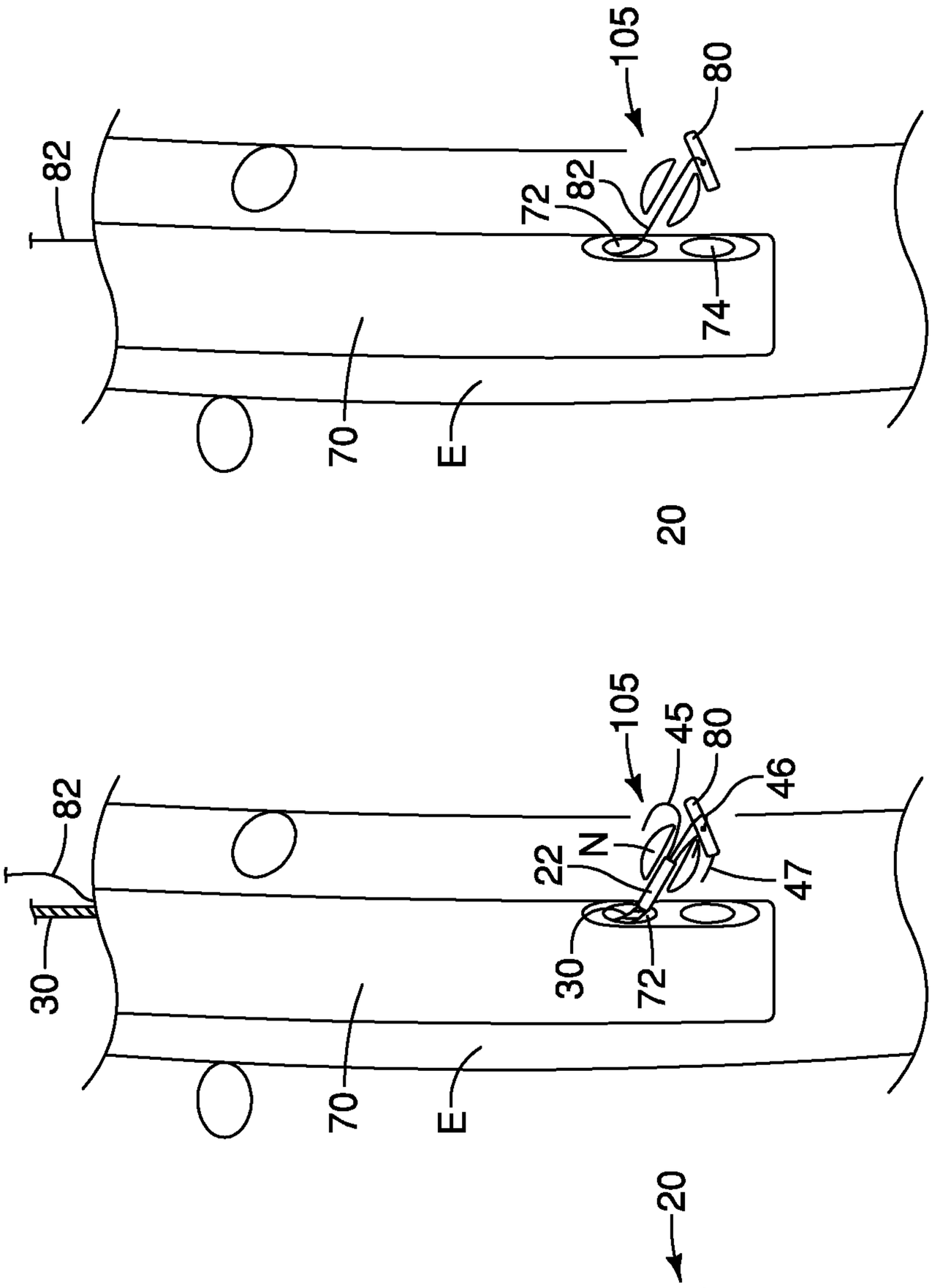


FIG. 12

FIG. 11

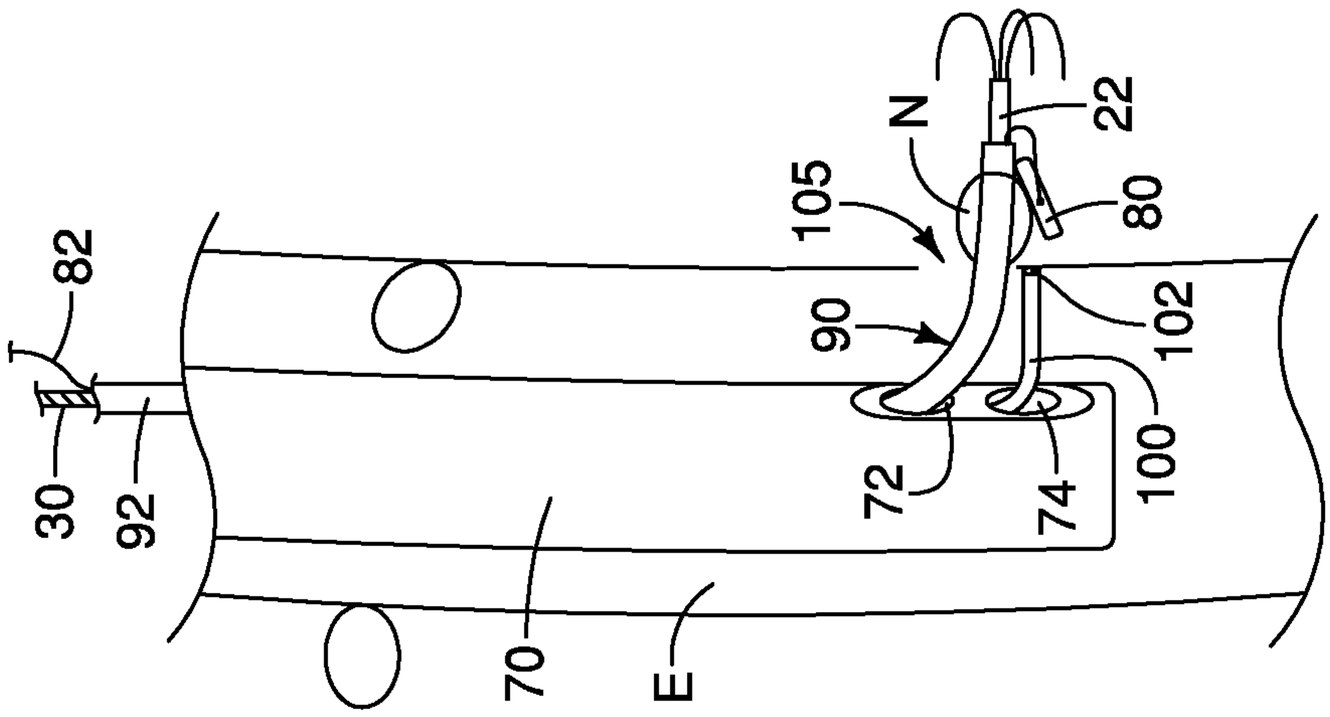
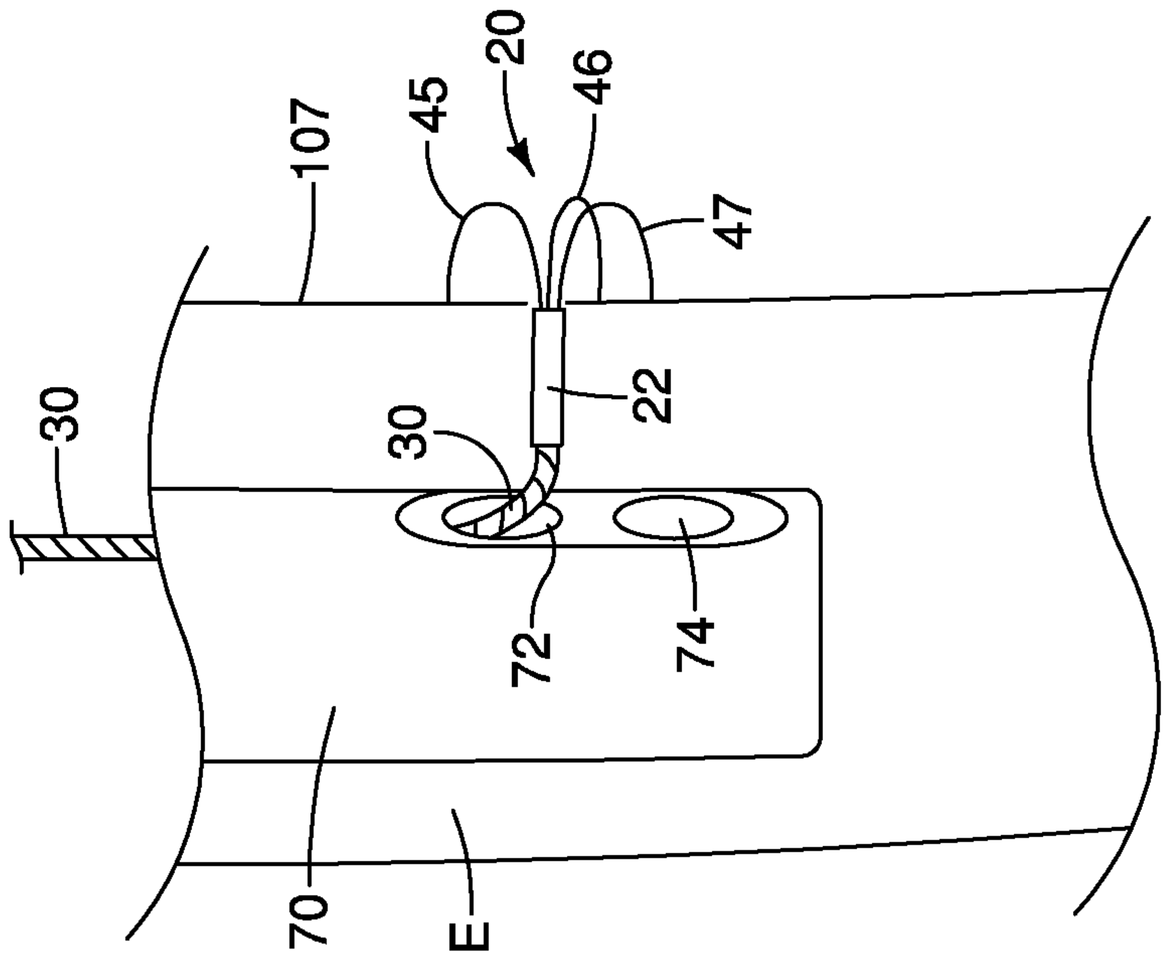


FIG. 10


107
45
20
46
47
30
22
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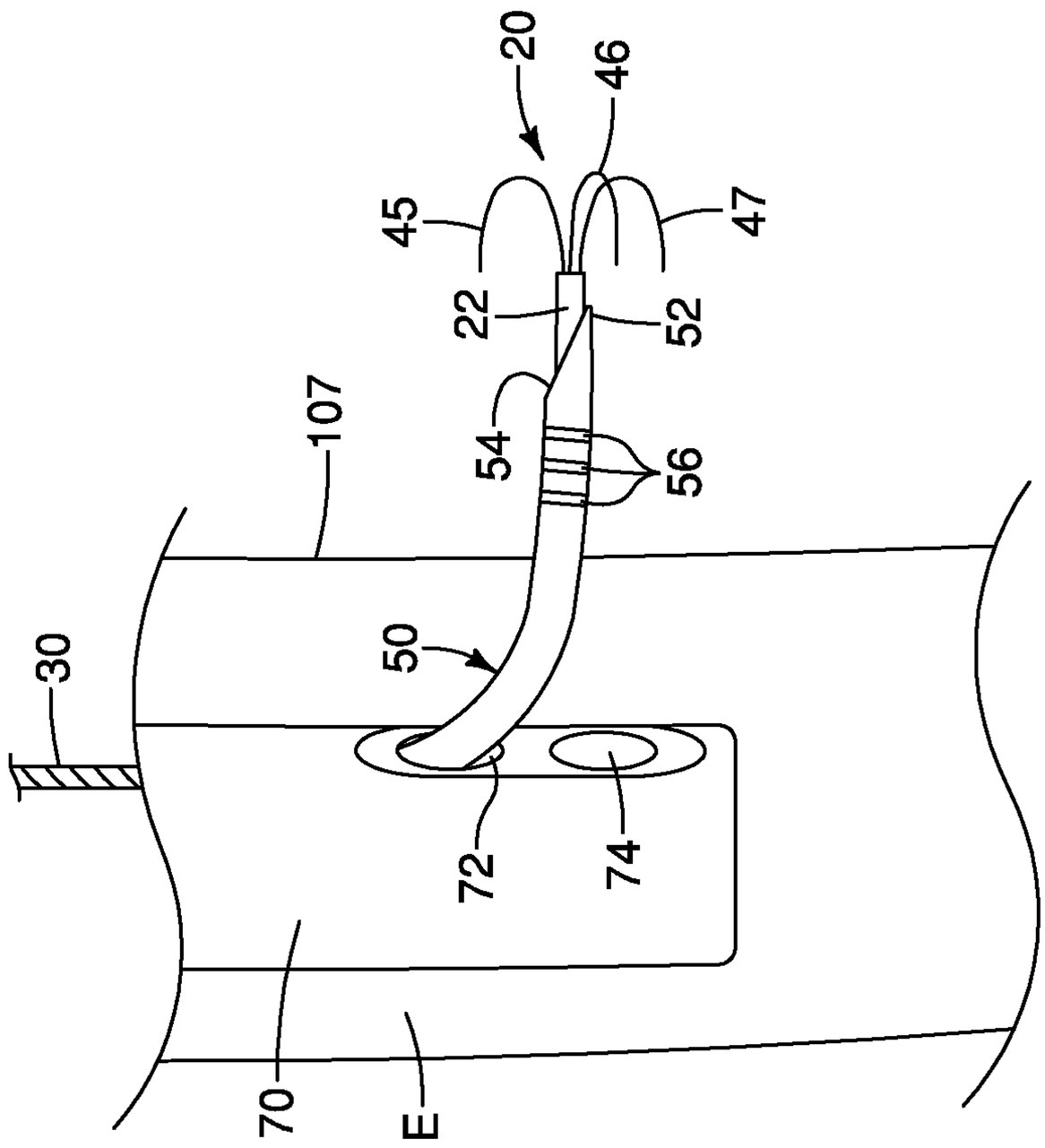
74
70
E

FIG. 14


20
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22
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70
E

FIG. 13

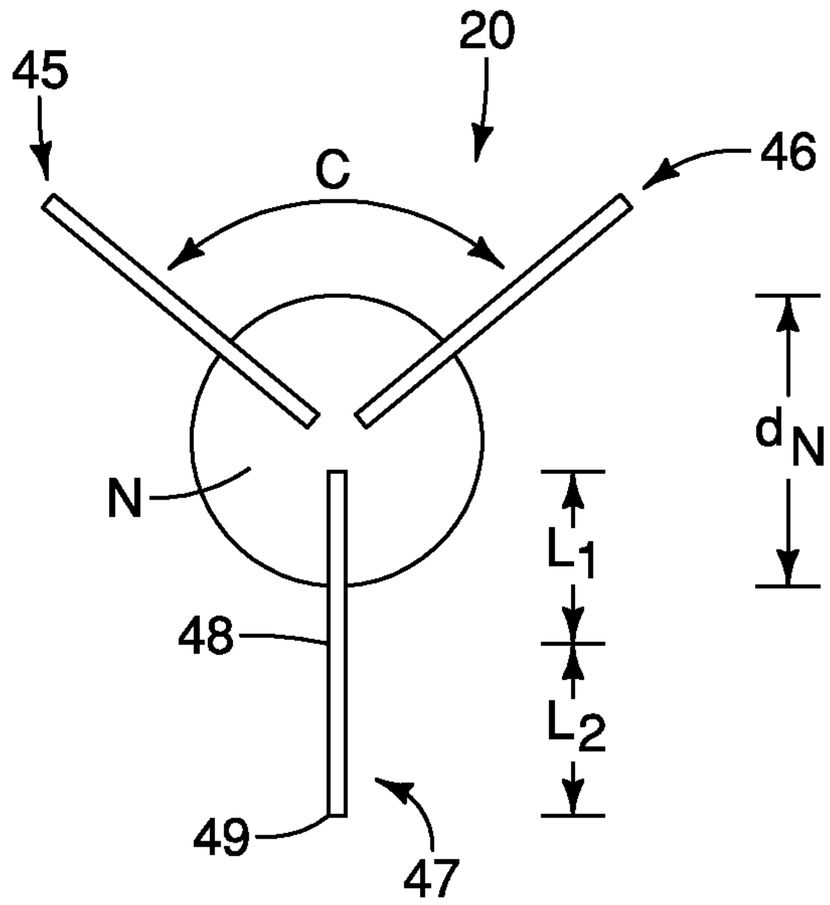

FIG. 15

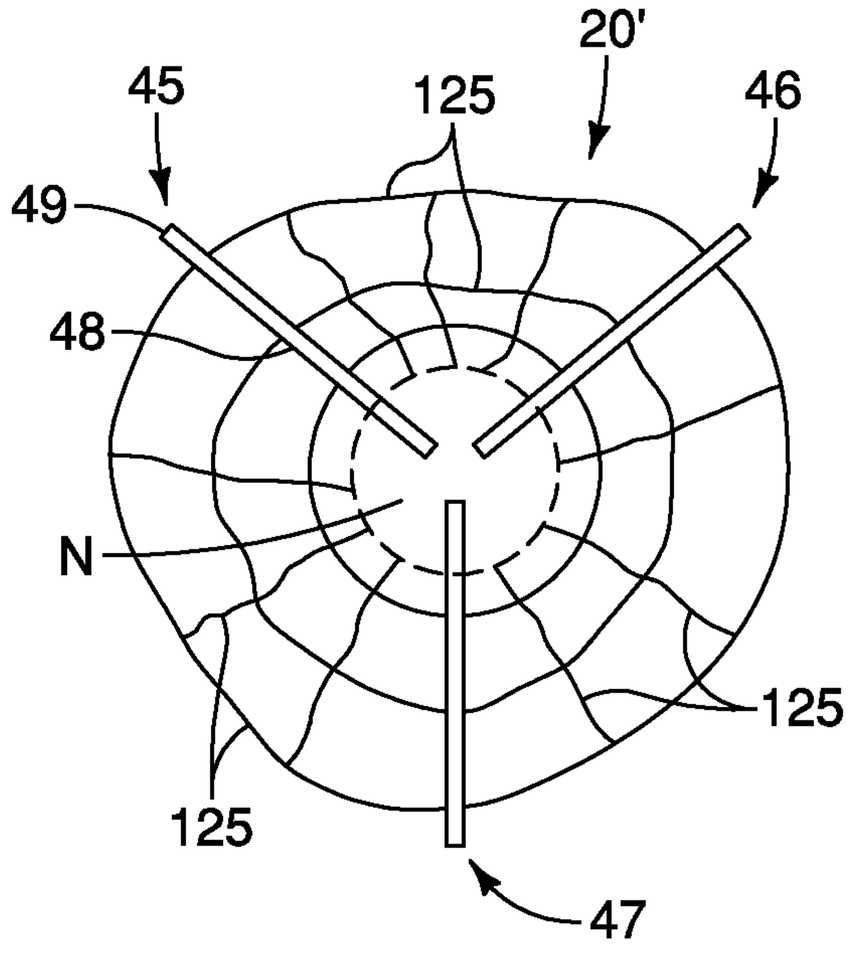

FIG. 16

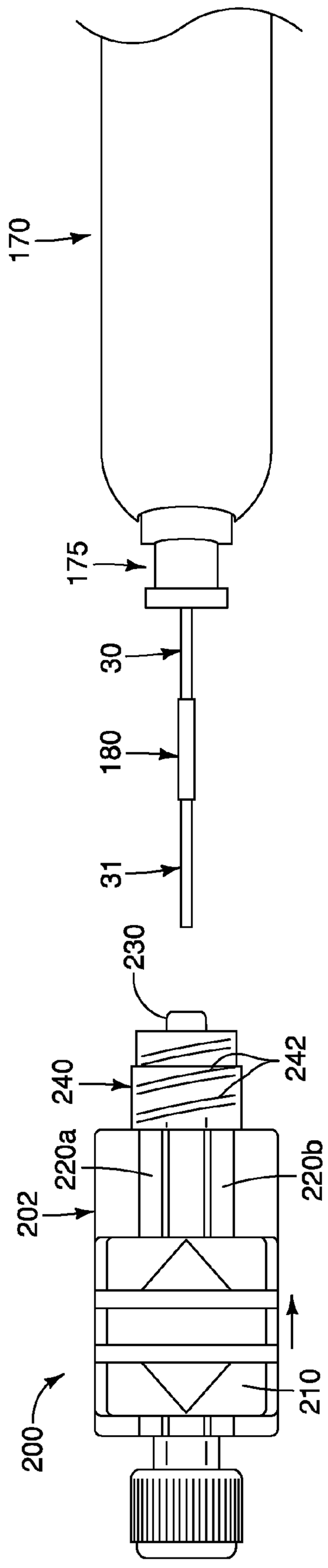

FIG. 17A

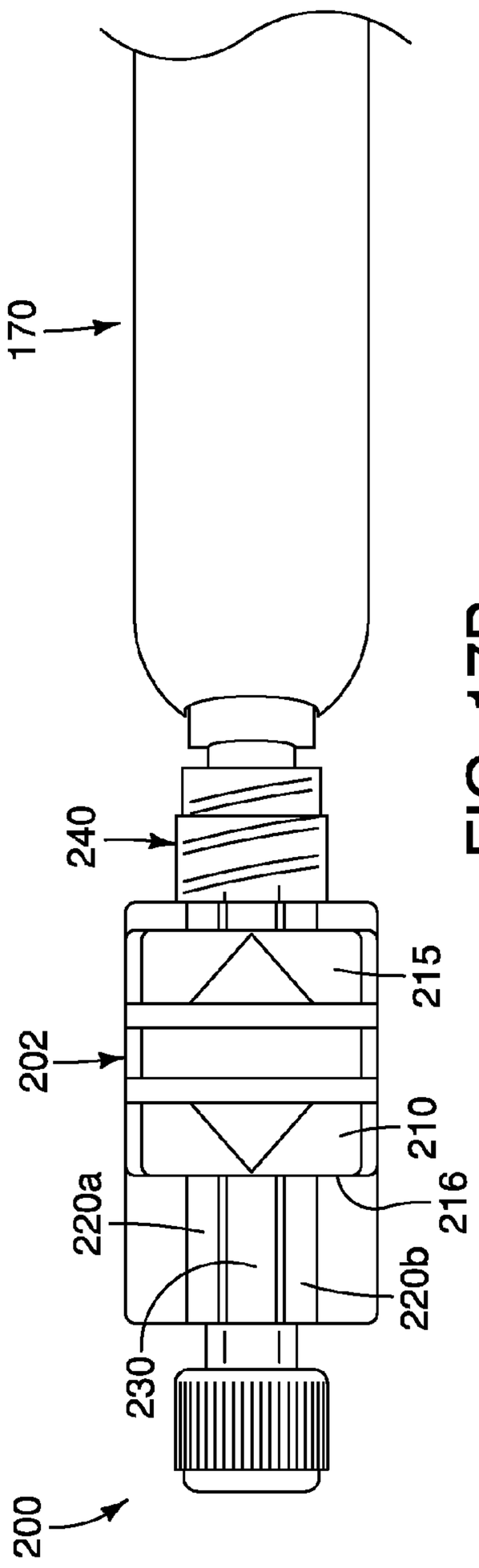

FIG. 17B

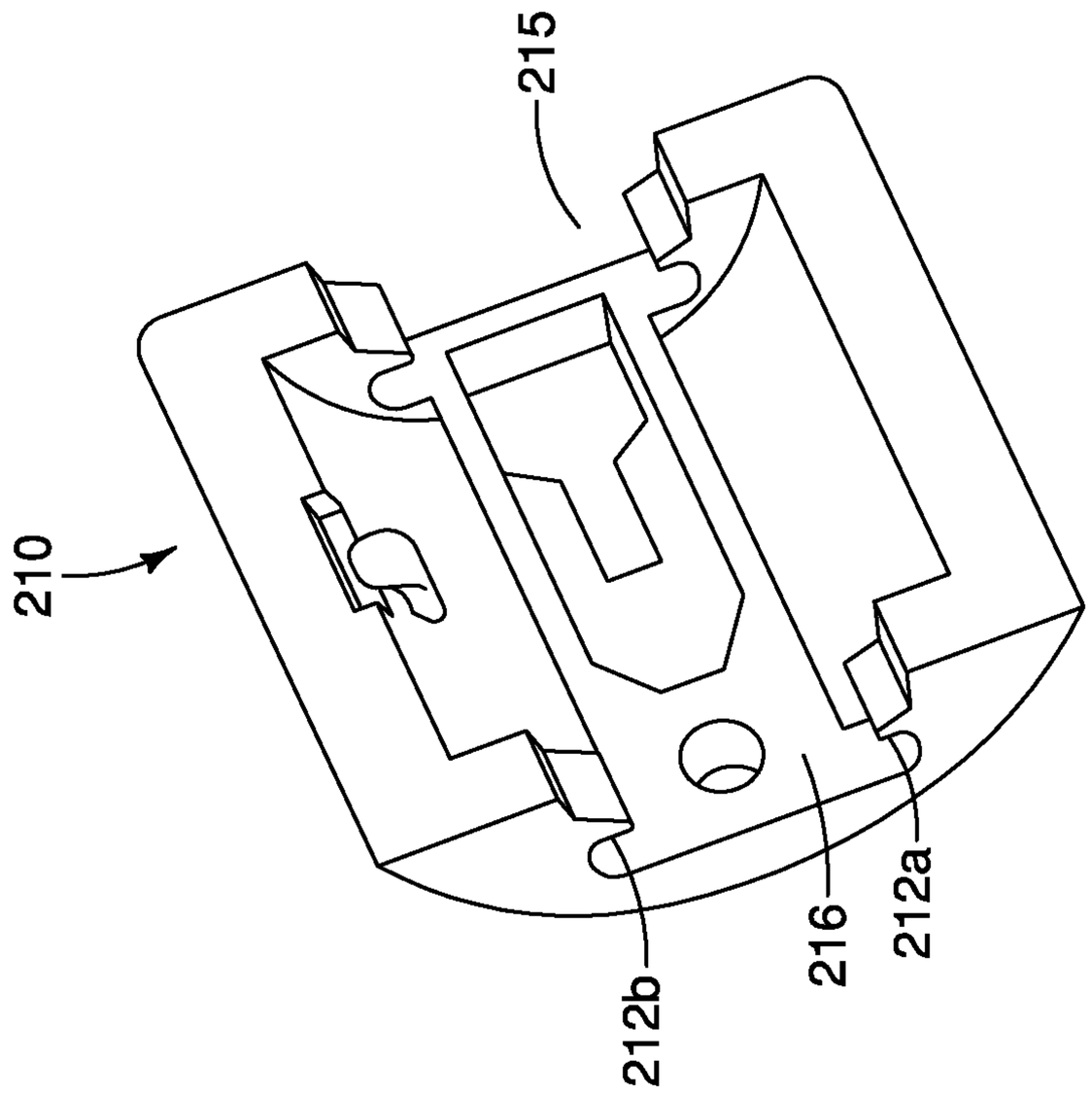

FIG. 19

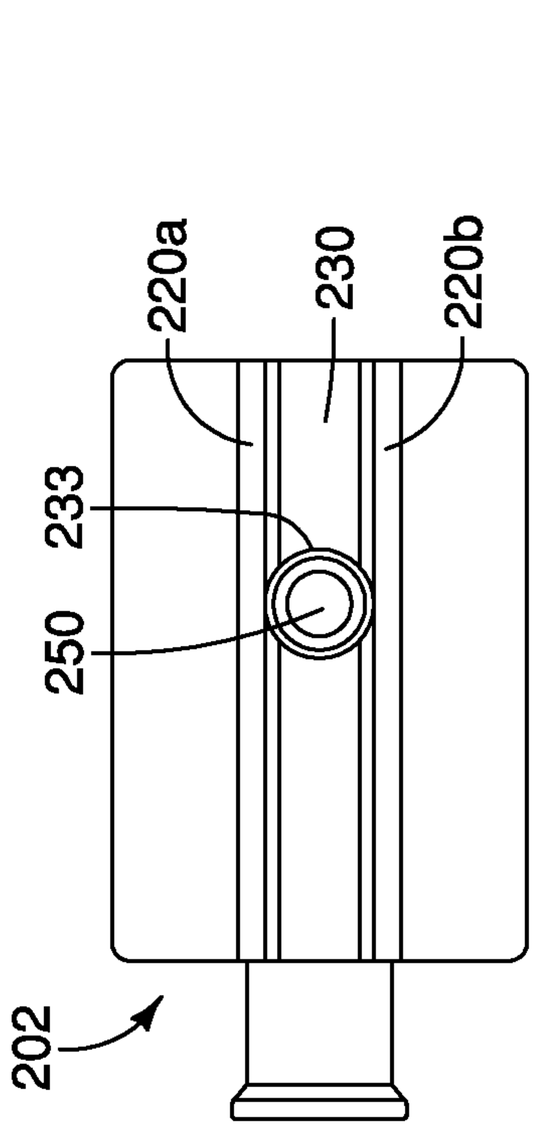

FIG. 18A

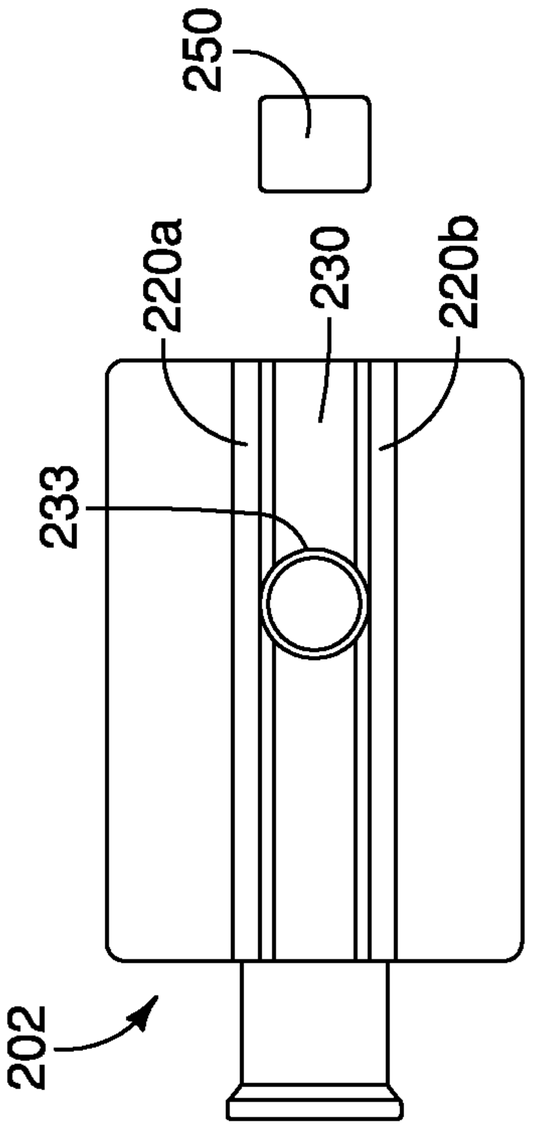

FIG. 18B

APPARATUS AND METHODS FOR REMOVING LYMPH NODES OR ANCHORING INTO TISSUE DURING A TRANSLUMENAL PROCEDURE

PRIORITY CLAIM

This invention claims the benefit of priority of U.S. Provisional Application Ser. No. 61/090,115, entitled "Apparatus and Methods for Removing Lymph Nodes or Anchoring into Tissue During a Translumenal Procedure," filed Aug. 19, 2008, the disclosure of which is hereby incorporated by reference in its entirety.

BACKGROUND

The present embodiments relate generally to medical devices, and more particularly, apparatus and methods suitable for removing lymph nodes or providing a tissue anchor during a translumenal medical procedure.

Translumenal procedures generally encompass the formation of perforations in visceral walls to gain access to adjacent structures of the body. For example, culdoscopy was developed over 70 years ago, and involves transvaginally accessing the peritoneal cavity by forming a perforation in the cul de sac. This access to the peritoneal cavity allows medical professionals to visually inspect numerous anatomical structures, as well as perform various procedures such as biopsies or other operations. Many translumenal procedures for gaining access to different body cavities using other bodily lumens have also been developed. Generally, each of the translumenal procedures require the use of several different medical instruments, such as a cutting instrument to form the perforation, an endoscope or other visualizing device to inspect the area or otherwise perform some procedure, and then a closure instrument to close the perforation.

Relatively recent attempts have focused on the translumenal removal of lymph nodes. See Fritscher-Ravens, et al., "*Endoscopic Transgastric Lymphadenectomy Using Endoscopic Ultrasound For Selection and Guidance,*" *Gastrointestinal Endoscopy*, Vol. 63, Issue 2, pp. 302-306 (2006). In this article, selected lymph nodes were punctured with a 19-gauge Endoscopic Ultrasound (EUS) needle. A metal anchor with thread, loaded onto the needle, was placed across the lymph node to pull the node toward the stomach. After gastric-wall dissection with a needle knife at the point of emergence of the thread, the nodes were removed by pulling on the thread and the anchor. The gastric incision then was closed with an endoscopic suturing system.

While the above-referenced article provides a foundation for translumenal removal of lymph nodes, it is an emerging approach and merits the development of new and improved techniques.

SUMMARY

In a first embodiment according to the teachings of the present invention, apparatus and methods are provided for facilitating removal of one or more lymph nodes. The apparatus preferably comprises an expandable device including at least one deployable member having contracted and expanded states. In the expanded state, the deployable member may comprise a parachute-shaped configuration, umbrella-shaped configuration, or other configuration sized to at least partially circumferentially surround the lymph node. The deployable member may be delivered to a location distal to the lymph node using an insertion tool adapted to be disposed beyond the lymph node.

In one exemplary method of use, the insertion tool may be advanced beyond the lymph node, and a T-anchor coupled to a suture may be advanced through the insertion tool and ejected at a location distal to the lymph node. Retraction of the suture causes the T-anchor to engage the lymph node and promotes stabilization of the lymph node. Subsequently, the deployable member is advanced distal to the lymph node in the contracted state, using the same insertion device or another insertion device, and assumes the expanded state when advanced distal to the insertion tool and the lymph node.

The lymph node may be removed translumenally through a visceral wall, such as the stomach or esophagus. In one method step, an opening may be created in the visceral wall to facilitate removal of the lymph node. The deployable member may be proximally retracted to engage and retract the lymph node in a proximal direction through the opening in the visceral wall to facilitate removal of the lymph node. A removal device, such as a snare, may then be used to disengage the lymph node from surrounding tissue.

The deployable member may comprise a nickel-titanium alloy that is configured to self-expand to the parachute-shaped configuration or another suitable configuration. The parachute-shaped configuration may be suitable for at least partially circumferentially surrounding the lymph node, and may comprise a strength sufficient to engage and retract the lymph node. In one embodiment, three parachute-shaped deployable members are provided, although greater or fewer deployable members may be used.

In an alternative embodiment, the expandable device may be anchored into tissue to promote stability of a system during a medical procedure. In this method, an insertion tool may be advanced through a first channel of an endoscope, and may pierce through an outer portion of the visceral wall. The expandable device is advanced through the insertion tool and the deployable member is deployed distal to the insertion tool. Upon proximal retraction, the deployable member anchors into the outer portion of the visceral wall. Such anchoring promotes stabilization of the system when additional components are advanced, or procedures performed, through the first channel or a second channel of the endoscope.

Other systems, methods, features and advantages of the invention will be, or will become, apparent to one with skill in the art upon examination of the following figures and detailed description. It is intended that all such additional systems, methods, features and advantages be within the scope of the invention, and be encompassed by the following claims.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention can be better understood with reference to the following drawings and description. The components in the figures are not necessarily to scale, emphasis instead being placed upon illustrating the principles of the invention. Moreover, in the figures, like referenced numerals designate corresponding parts throughout the different views.

FIG. **1** is a perspective view of a distal end of an expandable device.

FIG. **2**A is a perspective view of a distal region of an insertion tool and the expandable device of FIG. **1**.

FIG. **2**B is a perspective, cut-away view illustrating the expandable device of FIG. **1** in a delivery configuration.

FIG. **3** is a schematic view illustrating a mediastinal cavity including lymph nodes.

FIGS. **4-12** are exemplary method steps that may be used to remove a lymph node using the expandable device of FIGS. **1-2**B.

FIGS. **13-14** are exemplary method steps illustrating use of the expandable device of FIGS. **1-2**B as a visceral wall anchor.

FIG. **15** is an end view of a lymph node and the expandable device of FIGS. **1-2**B in a deployed state.

FIG. **16** is an end view of a lymph node and an alternative expandable device in a deployed state.

FIGS. **17**A-**17**B are side schematic views of a control assembly that may be remvoably coupled to a handle, as shown in uncoupled and coupled states, respectively.

FIGS. **18**A-**18**B are side schematic views of the control assembly of FIGS. **17**A-**17**B with a slidable actuator removed for illustrative purposes.

FIG. **19** is a rear perspective view of a slidable actuator of the control assembly of FIGS. **17**A-**17**B.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

In the present application, the term "proximal" refers to a direction that is generally towards a physician during a medical procedure, while the term "distal" refers to a direction that is generally towards a target site within a patient's anatomy during a medical procedure.

Referring now to FIG. **1**, a first embodiment of an expandable device **20** is shown. In this embodiment, the expandable device **20** comprises at least one tube member **22** having a proximal end **24** and a distal end **26**. The expandable device **20** further comprises a distal deployment mechanism **42**. In the embodiment of FIG. **1**, the distal deployment mechanism **42** comprises three deployable members **45-47**. The deployable members **45-47** extend distally from the distal end **26** of the tube member **22**, as shown in FIG. **1**. Further, a control member **30** may extend proximally from the proximal end **24** of the tube member **22**.

The deployable members **45-47** each may be affixed relative to the tube member **22**. In one embodiment, each of the deployable members **45-47** may be separate and discrete elements. Accordingly, three separate deployable members may be provided. Specifically, the three deployable members **45-47** may be coupled to the distal end **26** of the tube member **22** using an adhesive, frictional fit, mechanical device or other suitable mechanism.

While three deployable members **45-47** are depicted, it will be apparent that greater or fewer deployable members may be employed. Moreover, the deployable members **45-47** may comprise any shape suitable for engaging, penetrating and/or abutting tissue, or for engaging and capturing a lymph node, for purposes explained further below, and need not necessarily assume the expanded shape depicted in FIGS. **1-2**A.

The tube member **22** may comprise any suitable shape and material. Solely by way of example, the tube member **22** may comprise stainless steel or a biocompatible plastic. The tube member **22** may be cylindrically-shaped, as depicted in FIG. **1**, which may facilitate insertion through a lumen of an insertion tool **50**.

Alternatively, the tube member **22** may be omitted entirely in the case where proximal regions of the deployable members **45-47** are collected together, and preferably affixed together, for example, using a solder or weld. In the latter example, the deployable members **45-47** may be affixed together and soldered or welded directly to a distal portion of the control member **30**, or the deployable members **45-47** may be integrally formed as a distal extension of the control member **30**. Further, a plurality of wire members may be braided or twisted together along a main portion of their length, but comprise distal regions configured to deploy to the parachute or umbrella-shaped configurations shown herein, or another configuration suitable for engaging the lymph node

The deployable members **45-47** each comprise a contracted delivery configuration, as shown in FIG. **2**B, and further comprise an expanded deployed configuration, as shown in FIGS. **1-2**A. In one embodiment, each of the deployable members **45-47** may comprise a parachute or umbrella-shaped configuration in the expanded state, or another configuration suitable for engaging the lymph node, such as a bent or L-shaped configuration.

For example, in the parachute or umbrella-shaped configurations shown, the deployable members **45-47** may comprise a curvature of about 90 to about 360 degrees in the expanded state, and more preferably about 180 degrees, as shown in FIGS. **1-2**A. Where the deployable members **45-47** "retroflex" and comprises a curvature of about 180 degrees, an apex **48** is formed and the end regions **49** of the deployable members are oriented substantially parallel to the tube member **22**. Moreover, the end regions **49** may be radially spaced apart from one another in the expanded state, as best seen in FIG. **1** and FIG. **15** below. In this configuration, the end regions **49** may be well-suited for engaging and capturing lymph nodes, or engaging, grasping and/or abutting tissue, as explained further below.

The dimensions of the expandable device **20** may be tailored based on a particular surgical procedure, a particular patient's anatomy and/or other factors. However, for illustrative purposes, in a lymph node removal procedure, a diameter d_N of an exemplary lymph node N may range from about 5 to about 15 mm, as depicted in FIG. **15**. In this example, the longitudinal length of the tube member **22** may range from about 2 mm to about 10 mm, the straightened (delivery or non-curved) length of the deployable members **45-47** may range from about 10 mm to about 50 mm, the outer diameter of the tube member **22** may range from about 0.3 mm to about 1.5 mm, and the outer diameter of the deployable members **45-47** may range from about 0.1 mm to about 0.5 mm.

Further, as shown in FIG. **15** below, a longitudinal length L_1 between a longitudinal axis L (see FIG. **1**) and the apex **48** may be about 3.2 to 16.0 mm, while a longitudinal length L_2 between the longitudinal axis L and the distal tip **49** may be about 6.4 to 32.0 mm. Such dimensions are provided for reference purposes only and are not intended to be limiting. Therefore, if the diameter d_N of an exemplary lymph node N ranges from about 5 to about 15 mm, the expandable device **20** will be configured to substantially or entirely surround, engage, and facilitate removal of the lymph node N, as depicted in FIG. **15** below.

Referring still to FIG. **15**, the three deployable members **45-47** may be spaced apart a circumferential distance C, which may be about 120 degrees. As will be apparent, the deployable members **45-47** may be spaced closer together or further apart to facilitate engagement and capture of a lymph node. If additional deployable members are provided, then the circumferential distance C between deployable members may decrease accordingly.

The deployable members **45-47** may comprise a shape-memory material, such as a nickel-titanium alloy (nitinol). If a shape-memory material such as nitinol is employed, the deployable members **45-47** may be manufactured such that they can assume the preconfigured expanded state shown in FIGS. **1-2**A upon application of a certain cold or hot medium. More specifically, a shape-memory material may undergo a

substantially reversible phase transformation that allows it to "remember" and return to a previous shape or configuration. For example, in the case of nitinol, a transformation between an austenitic phase and a martensitic phase may occur by cooling and/or heating (shape memory effect) or by isothermally applying and/or removing stress (superelastic effect). Austenite is characteristically the stronger phase and martensite is the more easily deformable phase.

In an example of the shape-memory effect, a nickel-titanium alloy having an initial configuration in the austenitic phase may be cooled below a transformation temperature (M_f) to the martensitic phase and then deformed to a second configuration. Upon heating to another transformation temperature (A_f), the material may spontaneously return to its initial, predetermined configuration, as shown in FIG. **1**. Generally, the memory effect is one-way, which means that the spontaneous change from one configuration to another occurs only upon heating. However, it is possible to obtain a two-way shape memory effect, in which a shape memory material spontaneously changes shape upon cooling as well as upon heating.

Alternatively, the deployable members **45-47** may be made from other metals and alloys that are biased, such that they may be restrained by the insertion tool **50** prior to deployment, but are inclined to return to their relaxed, expanded configuration upon deployment. Solely by way of example, the deployable members **45-47** may comprise other materials such as stainless steel, cobalt-chrome alloys, amorphous metals, tantalum, platinum, gold and titanium. The deployable members **45-47** also may be made from non-metallic materials, such as thermoplastics and other polymers. As noted above, the deployable members **45-47** may comprise any shape suitable for engaging and capturing lymph nodes, or engaging, grasping and/or abutting tissue, for purposes explained further below, and need not necessarily assume the curved shape depicted in FIGS. **1-2**A.

Referring to FIG. **2**B, the expandable devices **20** may be delivered to a target site in a patient's anatomy in the contracted configuration using an insertion tool **50**. In one embodiment, the insertion tool **50** comprises a needle-like body having a sharpened distal tip **52** and a hollow lumen **54**, as shown in FIGS. **2**A-**2**B. The insertion tool **50** may be manufactured from stainless steel or any other suitable material, and may comprise an endoscopic ultrasound (EUS), or echogenic, needle. Solely by way of example, the insertion tool **50** may comprise the EchoTip® Ultrasound Needle, or the EchoTip® Ultra Endoscopic Ultrasound Needle, both manufactured by Cook Endoscopy of Winston-Salem, N.C. Alternatively, the insertion tool **50** may comprise a non-echogenic needle, which may be visualized using an endoscope. As a further alternative, the insertion tool may comprise a conventional catheter **90** having at least one lumen sized to receive the expandable device **20**, as depicted in FIGS. **8-9** below.

The hollow lumen **54** of the insertion tool **50** may comprise an inner diameter than is larger than an outer diameter of the expandable device **20**. Therefore, the expandable device **20** may be loaded into the hollow lumen **54** in a delivery configuration, as shown in FIG. **2**B. In the delivery configuration, the deployable members **45-47** of the expandable device **20** may comprise a substantially longitudinally-oriented profile, i.e., oriented along a longitudinal axis of the insertion tool **50**. The expandable device **20** may be ejected from the insertion tool **50** by distally advancing a proximal region of the control member **30** while holding the insertion tool **50** steady, as explained in further detail below.

The insertion tool **50** may comprise one or more markers **56**, as shown in FIGS. **2**A-**2**B, which may be disposed near the distal end of the insertion tool **50**. The markers **56** may be configured to be visualized under fluoroscopy of other imaging techniques to facilitate location of the distal end of the insertion tool, for example, so that a physician may determine how far the insertion tool **50** has penetrated through a visceral wall, lymph node, or other matter, as explained further below. Optionally, a sheath member **58** having an inner diameter larger than an outer diameter of the insertion tool **50**, as shown in FIG. **2**A, may be longitudinally advanced over the insertion tool **50** to prevent inadvertent piercing of tissue.

Referring now to FIG. **3**, the expandable device **20** described above may be used to capture, engage, and otherwise facilitate removal of a lymph node N from a bodily region, such as the mediastinal cavity M. In the exemplary method of FIGS. **4-12** described below, a selected lymph node N may be removed from the mediastinal cavity M via the esophagus E.

In FIG. **3**, a patient's trachea T and lungs L are shown for reference purposes. Multiple mediastinal lymph nodes N are shown in FIG. **3**, including an uppermost mediastinal node above the left brachial vein, upper paratracheal nodes above the aortic arch and below the left brachiocephalic vein, lower paratracheal nodes in the vicinity of the aortic arch and main bronchus, and a paraesophageal node below the aortic arch. In FIGS. **4-12**, an enlarged illustration focuses on removal of the paraesophageal node below the aortic arch. However, any lymph node N, either situated within the mediastinal cavity or in another bodily passage, may be engaged or captured using the apparatus and methods described herein.

Referring to FIG. **4**, in a first step, an endoscope **70** is maneuvered into a patient's mouth and down through the esophagus E. The endoscope **70** may comprise a dual-channel endoscope having first channel **72** and second channel **74**. The first channel **72** may terminate at an exit port **73**, while the second channel **74** may terminate at an exit port **75**. While the lymph node procedure of FIGS. **4-12** may be performed using a single channel endoscope, it is preferred to utilize the multi-lumen endoscope **70**.

The endoscope **70** may comprise an echo endoscope or other device suitable for imaging. When the endoscope **70** is positioned within the esophagus E, various lymph nodes N may be observed using ultrasound techniques. The endoscope **70** may be used to detect a node N suitable for treatment, such as a malignant node desired to be removed from the patient.

In a next step, after a suitable lymph node N had been detected, a first insertion tool **50** may be advanced distally through the first channel **72** of the endoscope **70** towards the target lymph node N. As shown in FIG. **5**, the insertion tool **50** may be advanced distally through the exit port **73** of the endoscope **70** to pierce through the esophageal wall and through or around the target lymph node N. As noted above, the insertion tool **50** may comprise an EUS needle, such as the EchoTip® Ultrasound Needle, or the EchoTip® Ultran endoscopic Ultrasound Needle, both manufactured by Cook Endoscopy of Winston-Salem, N.C. The sharpened distal tip **52** of the insertion tool **50** facilitates piercing through the target lymph node N. The markers **56** of FIG. **2**A may facilitate in determining how far the insertion tool **50** has penetrated into and through the esophageal wall and the target lymph node N. Alternatively, the insertion tool **50** may be advanced around the target lymph node N, instead of directly through the node. Preferably, the sharpened distal tip **52** is advanced just distal to the target lymph node N, as depicted in FIG. **5**.

It should be noted that during advancement and placement of the insertion tool **50** beyond the target lymph node N, the hollow lumen **54** of the insertion tool **50** may be loaded with a visceral anchor or tissue anchor ("T-anchor") **80**, which is coupled to a suture **82**. The T-anchor **80** may be used for visceral wall stabilization, as explained in further detail below. As best seen in FIGS. **6-7**, the T-anchor **80** may comprise a crossbar having first and second ends, wherein the suture **80** is coupled to a central region of the crossbar between the first and second ends. One exemplary configuration of a T-anchor suitable for use in the present embodiments is described in greater detail in U.S. Patent Publication No. 2008/0132948, which is hereby incorporated by reference in its entirety. Another example of a suitable visceral anchor is disclosed in U.S. Pat. No. 5,123,914, which also is hereby incorporated by reference in its entirety.

Referring still to FIGS. **6-7**, with the insertion tool **50** disposed beyond the target lymph node N, the T-anchor **80** may be deployed. An inner stylet (not shown) may be disposed within the hollow lumen **54** of the insertion tool **50** at a location proximal to the T-anchor **80**. The inner stylet then may be advanced distally, while the insertion tool **50** is held steady, in order to distally eject the T-anchor **80** from the hollow lumen **54**, as depicted in FIG. **6**. It should be noted that during delivery of the T-anchor **80**, the suture **82** may be disposed within the hollow lumen **54** of the insertion tool **50**, as depicted in FIG. **6**, or alternatively may run along the outside of the insertion tool **50** within the first channel **72** of the endoscope **70**.

After the T-anchor **80** is ejected from the insertion tool **50**, the insertion tool **50** may be removed from within the first channel **72** of the endoscope **70**. At this time, the T-anchor **80** is disposed just distal to the target lymph node N, with the suture **82** disposed through the lymph node N and extending proximally through the first channel **72** of the endoscope **70**, as shown in FIG. **7**. The proximal end of the suture **82** may be manipulated by a physician to aid in stabilization, i.e., when the suture **82** is pulled proximally the T-anchor **80** may be tilted into a transverse position and may be caught by the lymph node N.

Referring now to FIGS. **8-9**, in a next step, the expandable device **20** of FIGS. **1-2**B may be delivered and deployed to engage, capture or otherwise facilitate removal of the target lymph node N. In this example, the expandable device **20** is loaded into a second insertion tool, which is in the form of a catheter **90** having a proximal end **92** and a distal end **94**. Alternatively, the expandable device **20** may be loaded through an insertion tool having a sharpened distal tip, such as an EUS needle similar to the insertion tool **50** described above. In a further alternative embodiment, the sheath member **58** described above, which may cover a sharpened insertion tool, may be used to deliver the expandable device in lieu of a separate catheter **90**.

The catheter **90** has a lumen disposed between the proximal end **92** and the distal end **94**. The expandable device **20** is loaded into the lumen of the catheter **90** in the delivery configuration shown in FIG. **2**B. It should be noted that the catheter **90** may be advanced directly over the suture **82** of the T-anchor **80** towards the target lymph node N. Therefore, both the suture **82** and the expandable device **20**, including the control member **30**, may be simultaneously disposed within the lumen of the catheter **90**, as depicted in FIGS. **8-9**.

Alternatively, a proximal region of the suture **82** outside of the body, or a distal region of the suture **82** near the visceral wall of the esophagus E, may be cut off prior to insertion of the device carrying the expandable device **20**. In this latter embodiment, if a new insertion device is used, such as a different endoscope, needle or catheter, to deliver the expandable device **20**, then it may be advanced towards the visceral wall of the esophagus E without the need to be advanced directly over the suture **82** along its entire length.

As shown in FIG. **8**, the catheter **90** may be advanced over the suture **82** and beyond the target lymph node N. Preferably, the proximal end of the suture **82** is tensioned while the catheter **90** is advanced distally beyond the esophageal wall and the target lymph node N, as depicted in FIG. **8**. The tensioning of the suture **82** may retract the T-anchor **80** against the target lymph node N, which may facilitate stabilization of the node and advancement of the catheter **90** through the node. If necessary, the suture **82** can be locked into place to temporarily secure the tension and positioning the T-anchor **80**. Without the stabilization via the T-anchor **80** and associated suture **82**, the endoscope **70** may deflect away from the esophageal wall when the catheter **90** is advanced distally through the esophageal wall and lymph node N.

Referring to FIG. **9**, after the distal end **94** of the catheter **90** has been advanced beyond the target lymph node N, the expandable device **20** may be deployed by advancing the control member **30** distally with respect to the endoscope **70**. This causes the deployable members **45-47** of the expandable device **20** to extend distal to the distal end **94** of the catheter **90**. When the deployable members **45-47** are no longer radially constrained by the catheter **90**, they may assume their predetermined expanded configurations.

Referring to FIG. **10**, a cutting device **100** may be used to enlarge the esophageal wall opening to facilitate extraction of the target lymph node N. The cutting device **100** may comprise a needle knife having an electrified cutting tip **102**. The cutting device **100** may be advanced through the second channel **74** of the endoscope **70** towards the target site. An opening **105** may be carefully formed around the other components, including the catheter **90**, as shown in FIG. **10**. Optionally, the catheter **90** may be proximally retracted and removed prior to insertion or actuation of the cutting device **100**.

Referring to FIG. **11**, in a next step, the expandable device **20** may be proximally retracted, by retracting the control member **30**, to cause the deployable members **45-47** to engage, capture, or otherwise facilitate removal of the target lymph node N. In particular, the substantially 180-degree parachute-shaped configuration of the deployable members **45-47** may substantially or entirely surround the target lymph node N, then urge the target lymph node N in a proximal direction at least partially through the opening **105** and towards the lumen of the esophagus E. At about the same time, the suture **82** may be proximally retracted to retract the T-anchor **80** in harmony with the retraction of the target lymph node N and the expandable device **20**.

Referring to FIG. **12**, in a next step, the expandable device **20** may be removed from engagement with the target lymph node N. In a first exemplary technique, the catheter **90** may be advanced distally over the deployable members **45-47**, preferably while the T-anchor **80** is tensioned via the suture **82**, to cause the deployable members **45-47** to assume the contracted configuration of FIG. **2**B. The catheter **90** and control member **30** then may be proximally retracted to remove the expandable device **20** from engagement with the target lymph node N.

In a second exemplary technique, the deployable members **45-47** may pull through the target lymph node N and assume the retracted configuration of FIG. **2**B when a predetermined force threshold is exceeded. In this example, the deployable members **45-47** will not retract when engaging and capturing the lymph node N, but may be configured to retract when a predetermined force threshold is exceeded, e.g., when the

lymph node N is held in place against the catheter **90** and/or the endoscope **70**. With the lymph node N held in place, further retraction of the control member **30** may force contraction of the deployable members **45-47** around or through the lymph node N and into the endoscope **70**. In preliminary testing, the deployable members **45-47** may be contracted with a force in a range of about 0.5 pond to about 2.0 pond, although they may be tailored to contract upon any other suitable force.

At this time, the target lymph node N therefore is disposed partially or entirely within the esophagus E, with the suture **82** disposed through the lymph node N and the T-anchor **80** disposed distal to the lymph node N, as shown in FIG. **12**. The cutting device **100** may be removed from the second channel **74** of the endoscope **70**, and a removal device, such as a polypectomy snare, may be advanced through the second channel **74** and positioned to surround the target lymph node N. Electrocautery then may be used to cut the target lymph node N from the surrounding tissue. It should be noted that the suture **82** coupled to the T-anchor **80** also may be cut off by the removal device. The T-anchor **80** may be removed or may pass naturally through the body, while the remaining suture **82** may pulled through the first channel **72** of the endoscope **70**.

In a final step, the visceral wall opening **105** created during the procedure may be closed using known techniques. As an example, the opening **105** may be closed using a suturing system by placing multiple anchors around the opening **105**, then tensioning the sutures in a purse-string fashion. Alternatively, clips or other devices may be used to effect closure of the opening **105**. The closure of the opening **105** may be performed through the first channel **72** and/or the second channel **74** of the endoscope **70**, which then is removed from the patient's body.

While FIGS. **4-12** have illustrated the use of one expandable device **20** for engaging, capturing or otherwise facilitating removal of a lymph node N located within the mediastinal cavity, the expandable device **20** disclosed herein may be useful in many other procedures performed through the stomach or other visceral walls. Further, the order of the method steps shown in FIGS. **4-12** may be varied, or some of the steps may be omitted. For example, while the use of the T-anchor **80** may be used for stabilization of the visceral wall and/or lymph node throughout the procedure, the T-anchor **80** may optionally be omitted.

Further, it will be appreciated that while a dual-channel endoscope **70** has been shown for performing the procedure, a single channel endoscope or other suitable insertion apparatus may be used to deliver the components and perform the procedure described above. Similarly, two different endoscopes may be used in succession, for example, a first endoscope may be used to detect a suitable lymph node, advance an EUS needle and deploy the T-anchor **80**, while a second endoscope may be advanced to the target site over the suture **82** of the T-anchor **80** and used to deploy the expandable device **20** and complete the procedure.

Further, it may be desirable to only use the insertion tool **50** to deliver both the T-anchor **80** coupled to the suture **82** and the expandable device **20** coupled to the control member **30**, without exchanging the insertion tool **50**. In this example, the T-anchor **80** may be loaded within the hollow lumen **54** of the insertion tool **50** at a location distal to the deployable members **45-47**. The suture **82** and the control member **30** may extend adjacent to one another within the hollow lumen **54**. In use, distal advancement of the control member **30** may cause the deployable members **45-47** to be distally advanced to initially eject the T-anchor **80** from the distal end of the insertion tool **50**, for purposes described above. Then, at a subsequent desired time, the deployable members **45-47** may be ejected from the insertion tool **50**. In this example, therefore, only one insertion tool **50** is used and does not need to be exchanged.

Referring now to FIGS. **13-14**, in an alternative embodiment, the expandable device **20** may be adapted to anchor into a visceral wall and/or other tissue to facilitate stabilization during a translumenal procedure using the dual-channel endoscope **70**. In a first method step, an insertion tool **50**, such as an EUS needle, is distally advanced through the first channel **72** of the endoscope **70** and pierces through the esophageal or other visceral wall, as generally set forth above. In this embodiment, the hollow inner lumen **54** of the insertion tool **50** may be loaded with the expandable device **20**. Upon desired placement of the insertion tool **50**, the control member **30** coupled to the expandable device **20** is advanced distally with respect to the insertion tool **50**. This causes the deployable members **45-47** of the expandable device **20** to extend distal to the insertion tool **50** and assume their predetermined expanded configurations, as shown in FIG. **13**.

The insertion tool **70** then may be retracted into the first channel **72** of the endoscope **50**, and the deployable members **45-47** then may be retracted proximally by retraction of the control member **30**. This causes the deployable members **45-47** of the expandable device **20** to engage, penetrate, abut or otherwise anchor into an outer portion **107** of the visceral wall. While a translumenal procedure is shown performed through the esophagus, other visceral wall, such as the stomach wall, may be perforated.

Such anchoring by the deployable members **45-47** of the expandable device **20** promotes stabilization of the system when additional components are advanced, or procedures performed, through the first channel **72** and/or the second channel **74** of the endoscope **70**. The expandable device **20** also may reduce the likelihood of the endoscope **70** deflecting away from the visceral wall as other components are advanced distally from the endoscope **70**.

For example, in the case of lymph node removal, a first expandable device **20** may be deployed through the first channel **72** to help stabilize the system, and then a second expandable device **20** may be deployed through the second channel **74** to facilitate removal of the lymph node, as described above. In this case, the first expandable device **20** may stabilize the endoscope **70** while the lymph node is cut and closing devices, such as anchors, are placed for closing the opening in the visceral wall.

Upon completion of the procedure, further retraction of the control member **30** may cause the deployable members **45-47** to pull through the visceral wall and assume the retracted configuration, shown in FIG. **2**B, within the first channel **72** of the endoscope **70**. As noted above, the deployable members **45-47** may assume the retracted configuration by advancing the insertion device **50** or catheter **90** distally, or it may pull through the visceral wall and assume the retracted configuration of FIG. **2**B when a predetermined force threshold is exceeded. Subsequently, any visceral wall openings formed during the procedure may be closed using known techniques, for example, purse-string suturing or clipping.

Referring now to FIG. **16**, in an alternative embodiment, an expandable device **20'** comprises an additional capture member **125**. The capture member **125** may comprise one or more wires coupled to the deployable members **45-47**, for example, in the form of a flexible and expandable netting disposed between the deployable members **45-47**, to facilitate engagement with and removal of a lymph node upon retraction of the expandable device **20'**. The capture member **125** may be

soldered or welded to selected regions along the deployable members **45-47**, e.g., in the vicinity of the respective apices **48** and distal tips **49**.

Referring now to FIGS. **17-19**, a control assembly **200** that may be removably coupled to a handle **170** is described. In FIG. **17**A, a proximal region **31** of the control member **30**, which as described above may be coupled to deployable members **45-47**, extends proximally from the handle **170**. The handle **170** may be coupled to the proximal end of the insertion tool **50** described above, and the control member **30** may extend through the hollow lumen **54** of the insertion tool **50**, as explained above.

The control assembly **200** generally comprises a platform **202** having guide elements **220***a* and **220***b*, which may be in the form of longitudinally-oriented tracks. The guide elements **220***a* and **220***b* guide longitudinal movement of a slidable actuator **210** between unlocked and locked states, as shown in FIGS. **17**A-**17**B, respectively. As shown in FIG. **19**, a surface of the slidable actuator **210** comprises grooves **212***a* and **212***b*, which are configured to securely slide along the guide elements **220***a* and **220***b* of the platform **202**.

The control assembly **200** further comprises tubing **230** extending between the guide elements **220***a* and **220***b* along at least a portion of its length. As shown in FIGS. **18**A-**18**B, the tubing **230** may comprise a lateral bore **233** formed therein, which is generally sized to receive a stopper **250**. Notably, in FIGS. **18**A-**18**B, the slidable actuator **210** has been removed from the platform **202** for illustrative purposes, while in FIG. **18**B, the stopper **250** has been removed from the bore **233** of the tubing **230** for illustrative purposes.

The control assembly **200** further comprises an engaging region **240**, which may partially surround the tubing **230**, as shown in FIG. **17**A. The engaging region **240** of the control assembly **200** may engage a proximal region **175** of the handle **170**, as shown in FIG. **17**B. For example, threading **242** on the engaging region **240** may engage complementary threading (not shown) on the proximal region **175** of the handle **170**.

When the control assembly **200** is unattached to the handle **170**, as shown in FIG. **17**A, an exchange of components may take place. For example, after the deployable members **45-47** coupled to the control member **30** have engaged a lymph node or other tissue, as explained above, the insertion tool coupled to the handle **170** may be proximally removed over the length of the control member **30**. Subsequently, another insertion tool may be distally advanced over the control member **30**, while the control member **30** and the deployable members **45-47** remain engaged with the lymph node or other tissue.

If it becomes desirable to proximally advance or retract the control member **30**, and thus the deployable members **45-47**, along with the handle **170**, then the control assembly **200** is coupled to the handle **170** as shown in FIG. **17**B. The slidable actuator **210** then is distally advanced along the guide elements **220***a* and **220***b*, as described above. Notably, the slidable actuator has a distal end **215** having a relatively deep recess, which tapers to a relatively shallow recess at a proximal end **216**, as shown in FIG. **19**. Thus, with distal advancement of the slidable actuator **210**, a shallower region of the slidable actuator **210** begins to cover the stopper **250**, and the underside of the slidable actuator **210** progressively engages the stopper **250**. The slidable actuator **210** therefore urges the stopper **250** radially inward in the position shown in FIG. **17**B, and the stopper **250** presses radially inward upon the tubing **230**. Since the proximal region **31** of the control member **30** is disposed within the tubing **230**, inward compression of the tubing **230**, via the stopper **250**, pinches upon the control member **30**. In this state, the control assembly **200** securely grasps the proximal region **31** of the control member **30** positioned adjacent to the bore **233**. Optionally, a cannula **180** may be soldered or otherwise secured to the proximal region **31** of the control member **30** to provide a locally increased profile that may facilitate grasping of the control member **30** by pinching of the tubing **230**. When it is desired to remove the handle **170** and insertion tool again, the slidable actuator **210** is moved back proximally to the state of FIG. **17**A, thus releasing the stopper **250** and the engagement of the tubing **230** with the control member **30**.

While various embodiments of the invention have been described, the invention is not to be restricted except in light of the attached claims and their equivalents. Moreover, the advantages described herein are not necessarily the only advantages of the invention and it is not necessarily expected that every embodiment of the invention will achieve all of the advantages described.

We claim:

1. A method for facilitating removal of a lymph node, the method comprising:

providing an expandable device comprising at least one deployable member having contracted and expanded states;

advancing at least a portion of the expandable device beyond the lymph node with the deployable member in the contracted state;

deploying the deployable member at a location distal to the lymph node, wherein the deployable member begins to deploy distal to the distal end of the lymph node, and wherein the deployable member, in the expanded state, comprises a configuration sized to at least partially circumferentially surround the lymph node; and

proximally retracting the expandable device to cause the deployable member to engage the lymph node.

2. The method of claim **1** wherein advancing at least a portion of the expandable device through the lymph node further comprises:

advancing an insertion tool through the lymph node, wherein the insertion tool comprises a hollow lumen, and wherein the expandable device is disposed within the hollow lumen with the deployable member in the contracted state; and

advancing the deployable member distal to the insertion tool to cause the deployable member to expand.

3. The method of claim **2** wherein the deployable member self-expands into a parachute-shaped configuration in the expanded state when no longer constrained by the insertion tool.

4. The method of claim **1** further comprising:

providing a T-anchor coupled to a suture, wherein the T-anchor is disposed within a hollow lumen of an insertion tool;

advancing the insertion tool distally beyond the lymph node;

ejecting the T-anchor from the insertion tool at a location distal to the lymph node; and

retracting the suture to cause the T-anchor to engage the lymph node and promote stabilization of the lymph node.

5. The method of claim **4**, further comprising:

removing the insertion tool from within the lymph node;

providing a catheter having a lumen, wherein the expandable device is disposed for delivery within the lumen of the catheter; and

distally advancing the catheter through the lymph node while tensioning the suture to stabilize the lymph node.

6. The method of claim 1, wherein the lymph node is removed translumenally through a visceral wall, the method further comprising:

creating an opening in the visceral wall to facilitate removal of the lymph node,

engaging the lymph node with the expandable device and retracting the expandable device to move the lymph node in a proximal direction through the visceral wall.

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